Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 75.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Stelara IV (ustekinumab)

I. Policy:
Stelara IV (ustekinumab)

II. Purpose/Objective:
To provide a policy of coverage regarding Stelara IV (ustekinumab)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Stelara (ustekinumab) is a fully humanized immunoglobulin G1 monoclonal antibody that targets the p40 subunit of human IL-12 and IL-23.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature

Stelara IV (ustekinumab) will be considered medically necessary for the commercial, exchange, and CHIP lines of business when all of the following criteria are met:

Crohn's Disease (CD)

- Prescription must be written by a gastroenterologist **AND**
- Member must be at least 18 years of age **AND**
- Medical record documentation of moderately to severely active Crohn's disease **AND**
- Medical record documentation that Stelara is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of three (3) of the following medications: Humira*, Cimzia*, Entyvio*, infliximab (or biosimilar) *, or Tysabri* **AND**
- Medical record documentation of Stelara 130mg vials as IV infusion (for induction therapy)

*Requires Prior Authorization

AUTHORIZATION DURATION: Approval will be given for an initial authorization duration of **six (6) months**.

QUANTITY LIMIT:
Initial Authorization:

- One-time authorization:
  - Facets Rx Count: 520 (J3358 – Ustekinumab IV)
  - Darwin Quantity Limit: 104 mL per 56 days GPI 14 for Stelara 130 mg vial
  - Darwin Quantity limit: 1mL per 56 days GPI 14 for Stelara 90mg Syringe

Ulcerative Colitis

- Prescription must be written by a gastroenterologist **AND**
- Member must be at least 18 years of age **AND**
- Medical record documentation of moderately to severely active ulcerative colitis **AND**
- Medical record documentation that Stelara is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of three (3) of the following medications: Humira*, Entyvio*, Rinvoq*, Simponi*, Xeljanz/Xeljanz XR*, and/or infliximab (or biosimilar)* **AND**
- Medical record documentation of Stelara 130mg vials as IV infusion (for induction therapy)

*Requires Prior Authorization

AUTHORIZATION DURATION: Approval will be given for an initial authorization duration of six (**6) months**.

QUANTITY LIMIT:
Initial Authorization:

- One-time authorization:
  - Facets Rx Count: 520 (J3358 – Ustekinumab IV)
  - Darwin Quantity Limit: 104 mL per 56 days GPI 14 for Stelara 130 mg vial
  - Darwin Quantity limit: 1mL per 56 days GPI 14 for Stelara 90mg Syringe

Stelara IV (ustekinumab) will be considered medically necessary for the Medicare line of business when all of the following criteria are met:

Crohn's Disease (CD)

- Prescription must be written by a gastroenterologist **AND**
- Member must be at least 18 years of age **AND**
- Medical record documentation of moderately to severely active Crohn's disease **AND**
- Medical record documentation that Stelara is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of Stelara 130mg vials as IV infusion (for induction therapy)

AUTHORIZATION DURATION: Approval will be given for an initial authorization duration of **six (6) months**.

QUANTITY LIMIT:
Initial Authorization:

- One-time authorization:
  - Facets Rx Count: 520 (J3358 – Ustekinumab IV)

Ulcerative Colitis

- Prescription must be written by a gastroenterologist **AND**
- Member must be at least 18 years of age **AND**
- Medical record documentation of moderately to severely active ulcerative colitis **AND**
- Medical record documentation that Stelara is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of Stelara 130mg vials as IV infusion (for induction therapy)

AUTHORIZATION DURATION: Approval will be given for an initial authorization duration of six (**6) months**.

QUANTITY LIMIT:
Initial Authorization:

- One-time authorization:
  - Facets Rx Count: 520 (J3358 – Ustekinumab IV)

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Stelara [prescribing information]. Horsham, PA: Janssen Biotech Inc; March 2023.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 03/10/10

Revised: 09/13; 02/14 (add indication); 09/16/14; 12/30/14 (updated formulary alternatives criteria), 09/15/15 (joint counts removed), 7/19/16 (dosing criteria added), 3/21/17 (Crohn's disease), 3/20/18 (form alt, duplicate therapy), 4/24/18 (per DHS, grandfather), 5/15/18 (peds plaque psoriasis), 4/15/20 (ulcerative colitis, updated QLs), 1/19/21 (pediatric age), 12/23/22 (removal of Stelara SQ/PsO/PsA/reauth, Medicare Carve Out), 12/19/23 (Medicaid business segment), 12/31/23 (references added)

Reviewed: 02/12, 4/22/19, 2/1/20, 1/18/22 (Updated Darwin QLs)

MA UM Committee approval: 12/31/23